MAR 2 9 2000

K000154

HOOD LABORATORIES

510(k) Summary
as required by 21 CFR 807.92(c)

Contact Information:

Anthony M. Sacchetti
E. Benson Hood Laboratories
575 Washington Street
Pembroke, MA 02359

Product Names:

Trade Name: Eliachar Laryngeal Foam Stent
Catalog Code: ELL-1

Product Description:

This device is a silicone foam filled laryngeal stent, designed to fit into and conform to the human larynx.

Intended Use:

The stent is to be used in patients with potential chronic aspiration after a partial laryngectomy or during Laryngotracheal reconstruction for stenosis and laryngeal fracture.

Predicate Device:

Hood Laryngeal Stent

Summary of Technological Similarities and Differences with the Predicate Device:

The external shape of the stent is similar to its predicate device, the Hood Laryngeal Stent. The stent is a softer structure that confirms to individual larynxes. The new stent offers a strap with neck plate, eliminating the need for suturing to the exterior of the neck.

A M Sacchetti
(signature)

Anthony M. Sacchetti
(typed name)

1-12-00
(date)

K000154
(510k number)

575 Washington Street, Pembroke, MA 02359 USA • 1-800-942-5227 • (781) 826-7573 • FAX: (781) 826-3899

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2000

Mr. Anthony M. Sacchetti
Quality Manager
E. Benson Hood Laboratories
575 Washington Street
Pembroke, MA 02359

Re: K000154
Trade Name: Eliachar Laryngeal Foam Stent
Regulatory Class: Unclassified
Product Code: 77FWN
Dated: January 12, 2000
Received: January 19, 2000

Dear Mr. Sacchetti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000154

Device Name: Eliachar Laryngeal Foam Stent

Indications For Use:

The stent is to be used in patients with potential chronic aspiration after a partial laryngectomy or during Laryngotracheal reconstruction for stenosis and Laryngeal fracture.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000154

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)